



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2003

Ms. Lydia B. Biggie
Vice President
NeoGen Technologies, Inc.
5353 NW 35th Avenue
Ft. Lauderdale, Florida 33309-6315

Re: K032301

Trade/Device Name: NeoGen One, Closed Wound Drain System
Part Number: NG9900
Regulation Number: 21 CFR 878.4780, 878.4020
Regulation Name: Powered suction pump, Occlusive wound dressing
Regulatory Class: II
Product Code: JCX, NAD
Dated: July 25, 2003
Received: July 25, 2003

Dear Ms. Biggie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

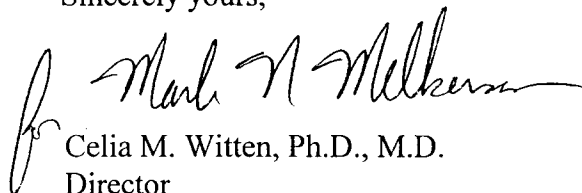
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over a horizontal line.

Celia M. Witten, Ph.D., M.D.
Director

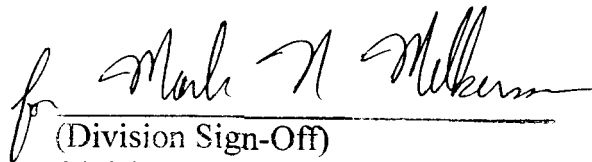
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K032301

2.0 INTENDED USE -

The NeoGen One device is indicated for patients who would benefit from a suction device, particularly as the use of that device may promote wound healing. This includes patients who would benefit from vacuum-assisted drainage and removal of infectious material or other fluids from wounds under influence of continuous and/or alternating vacuum pressure. This device is restricted to sale by, or on the order of, a physician or licensed practitioner.



(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

510(k) Number K032301